

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

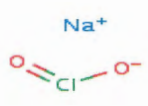


United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

January 23, 2013.

EPA Reg#: 89492-R		DP Barcode: 405381	
		Submission #: 922969.	
Product name: Dutrion Tablets.		Registrant: Dutrion North America Ltd.	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 01/20/13.		PSB received date: 09/27/12.	
CTT received date: 09/27/12		Science due date: 12/21/12.	
Formulation type: EUP <input checked="" type="checkbox"/>			
Integrated system: <input checked="" type="checkbox"/>	Non integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/>	Non food use: <input checked="" type="checkbox"/>
Action Code:		Date Completed:	
PC Code	CAS #	Active Ingredient Names	% wt (label)
020502	7758-19-2	Sodium chlorite	24
			
Test Lab: Wang Kuitao (author)			
MRID(s): 48925400 & 48925401.			
Approver: Karen P. Hicks		Approved date:	
Guideline: OPPTS 830 Guidelines Groups "A & B".			
Comments:			



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OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

January 23, 2013.

MEMORANDUM

Subject: Review for 89492-R

From: Salvador Rodriguez, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: Monisha Harris PM 32\Eliza Blair.
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Dutrion North America Ltd.

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium chlorite.....	20.00

BACKGROUND:

The registrant has submitted a Confidential Statement of Formula for the basic formulation and the OPPTS 830 Guidelines groups "A & B", to support the registration for the new disinfectant, sanitizer, fungicide & algacide, integrated, non-food and end-use product **Dutrion Tablet**. The product chemistry reviewer has received the following documents:

- A transmittal letter, dated 08/24/12. MRID #: 48925400.
- Certification with respect to citation of data, dated 08/23/12.
- Confidential Statement of Formula, dated 09/18/12, for the basic formulation.
- Draft label, dated 01/03/13.
- Study Titled: "Chemistry" OPPTS 830 Guidelines tables "A & B". MRID #: 48925401.
- Application for pesticide amendment, dated 08/19/12.
- MSDS, not dated.
- Data Matrix, dated 08/19/12.

FINDINGS:

1. The CSF, dated 01/03/13, for the basic formulation is revised.
2. The CSF and the label have the same nominal.
3. All certified limits meet the EPA standard certified limits The OPPTS Guidelines Series 830 Group A product chemistry data requirements applicable to end-use products have been met. MRID #48925401
4. The OPPTS guidelines series 830 Group B product chemistry data requirements applicable to end-use products have been met. MRID #: 48925401
7. The registrant indicated that five pilot-scale batches for the product **Dutrion Powder**, were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed in duplicate and the average of the two readings was used to express the weight % active ingredient (AI) in each sample. The results are the following:

Batch #	(%) Sodium chloride Average content
Duka20120510	19.8
Duka20120511	19.7
Duka21020512	19.75
Duke20120513	19.73
Duke20120514	19.78

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds CSF for the basic formulation, dated 01/03/13, for the integrated, non-food and end-use product EPARN 89492-R, and the OPPTS Guidelines Group A and OPPTS Guidelines Group B to be acceptable with the exception of the OPPTS series 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics". The results of the five batch analysis OPPTS 830.1700 are within the EPA standards certified limits.

RECONMENDATION:

On the CSF, the registrant should correct the CAS number for the effervescing agent. The correct CAS number is 56399-31-6. The registrant should submit the OPPTS series 830.6317 "Storage Stability" and 830.6320 "Corrosion Characteristics" when completed.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAI's used registered? Yes [] No []
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No [X]

c. Physical state of product:

Solid (tablet format)

d. The chemical IDs and analytical information (including that for the TGAI's), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient(s)

<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
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Sodium chlorite.....	20	19.0	21
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g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [X] No [] Not applicable []
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes ☐ No ☒
- 1.0% or more of methyl alcohol: Yes ☐ No ☒
- sodium nitrite at any level: Yes ☐ No ☒
- a toxic List 1 inert at any level: Yes ☐ No ☒
- arsenic in any form: Yes ☐ No ☒

c. If “yes” to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes ☐ No ☒

Note: Storage stability study is underway.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	48925401
830.1600 Description of Materials	A	48925401
830.1620 Production Process ²	A	48925401
830.1650 Formulation Process ³	A	48925401
830.1670 Formation of Impurities ⁴	A	48925401
830.1700 Preliminary Analysis ⁵	A	To be assigned
830.1750 Certified Limits ⁶	A	48925401
830.1800 Enforcement Analytical Method ⁷	A	48925401
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for manufacturing-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product is white.	48925401
830.6303 Physical State	A	The product is a solid tablet format.	48925401
830.6304 Odor	A	Chlorine (slight)	48925401
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	A	Incompatible with organic matter, sulfur, powdered, coal,	48925401
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	Incompatible with organic matter, sulfur, powdered, coal,	48925401
830.6315 Flammability/Flame Extension	A	Contact with combustible material may cause fire. This material increases the risk of fire and may aid combustion.	48925401
830.6316 Explodability	A	Sodium chloride is a powerful oxidizer, but will not explode on percussion unless in contact with oxidizable materials.	48925401
830.6317 Storage Stability	G	Storage stability study is underway.	48925401
830.6319 Miscibility ¹			
	A	The product is miscible with water based products.	48925401
830.6320 Corrosion Characteristics	G	Study is underway.	48925401
830.6321 Dielectric Breakdown Voltage	A	The product will not be used around electrical equipment	48925401
830.7000 pH ²	A	The pH of the product was reported to be between (6.0 – 6.5)	48925401
830.7050 UV/Visible Absorption	NR		
830.7100 Viscosity	A	The product is a solid.	48925401
830.7200 Melting Point/Melting Range	A	Chlorine dioxide (-59° C)	48925401

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7220 Boiling Point/Boiling Range	NR	The product is a solid.	48925401
830.7300 Density/Relative Density/Bulk Density	A	The density of the product was reported to be 1.6 g/mL (as a solid at 0°C.)	48925401
830.7370 Dissociation Constants in Water	NA	<i>[Not required for end-use products.]</i>	
830.7520 Particle size, fiber length, & diameter distribution.	A	Mesh 10 - 20.	48925401
830.7840/830.7860 Water Solubility	NA	<i>[Not required for end-use products.]</i>	
830.7950 Vapor Pressure	NA	<i>[Not required for end-use products.]</i>	

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water